



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Scopolamine Therapeutics For Depression And Bipolar Disorder

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Mental Health (NIMH), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Repurposed Therapeutics, Inc. (“Repurposed Therapeutics”) located in Tampa, Florida, to practice the inventions embodied in the patent application listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NIMH Technology Transfer Office [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Jennifer Wong, MS, Technology Development Coordinator, NIMH Technology Transfer Office, 35A Convent Drive, GE-400, Bethesda, MD 20892, phone number 301-480-4821, or wongje@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The following patents/patent applications are the intellectual properties to be licensed under the prospective agreement to Repurposed Therapeutics: U.S. Patent 8,859,585, issued October 14, 2014, entitled “Scopolamine for

the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-US-01]; Patent Cooperation Treaty (PCT) Application PCT/US2006/019335 filed May 18, 2006, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-PCT-02]; European Patent 1896025, issued December 28, 2011 entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-EP-03]; Canadian Patent 2610025, issued July 22, 2014, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-CA-04]; German Patent 602006026717.7, issued December 28, 2011, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-DE-07]; French Patent 1896025, issued December 28, 2011, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-FR-08]; UK Patent 1896025, issued December 28, 2011, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-GB-09], and US Patent No. Patent 9,707,220, issued July 18, 2017, entitled “Scopolamine for the Treatment of Depression and Anxiety” [HHS Ref. No. E-175-2004-0-US-10]. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective patent license may be worldwide, and the field of use may be limited to intranasal and intravenous scopolamine therapeutics for depression and bipolar disorder.

The invention pertains to the use of scopolamine for the treatment of depression and other indications associated with depression, such as the depressive phase of bipolar disorder. Although scopolamine has been employed in the treatment of nausea and motion sickness, the suitability of scopolamine for treating depression was unrecognized

prior to this invention. Current depression treatments can be ineffective in large percentage of patients and typically do not take effect until four weeks after administration. In contrast, treatment with scopolamine suggests it may be effective either as a stand-alone treatment or as a treatment for patients who are unresponsive to currently available drugs.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the NIMH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license.

Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Jennifer S. Wong

Technology Development Coordinator,

Technology Transfer Office,

National Institute of Mental Health.

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